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NDA APPROVALS FOR CALENDAR YEAR 2003
Updated through July 31, 2003

NDA NUMBER	DRUG NAME	GENERIC NAME	APPLICANT/ SPONSOR	CHEMICAL TYPE	THERAPEUTIC CLASS
21434	Xanax XR	Alprazolam	Pharmacia and Upjohn FR	3	S
21305	Sodium Iodide I-131	Sodium Iodide I-131	DraxImage	3,5	S
20414	Pyridostigmine Bromide	Pyridostigmine Bromide	US Army	3	P
21392	Cardizem LA	Diltiazem Hydrochloride	Biovail	3	S
21488	Eligard	Leuprolide Acetate	Atrix	3	S
21351	Oxytrol	Oxybutynin	Watson Labs (Utah)	3	S
21159	Loprox	Ciclopirox	Medicis	3	S
21438	InnoPran XL	Propranolol Hydrochloride	Reliant Pharms	5	S
21481	Fuzeon	Enfuvirtide	Roche	1	P
21367	Femring	Estradiol Acetate	Galen Ltd	2	S
21106	Somavert	Pegvisomant	Pharmacia and Upjohn	1	PV
21549	Emend	Aprepitant	Merck	1	P
21493	Zymar	Gatifloxacin	Allergan	3	S
21444	Risperdal	Risperidone	Johnson & Johnson	3	S
21158	Factive	Gemifloxacin Mesylate	LG Life	1	S
21271	Iprivask	Desirudin	Aventis Pharms	2	S
21475	Methylin	Methylphenidate Hydrochloride	Mallinckrodt	3	S
21598	Vigamox	Moxifloxacin Hydrochloride	Alcon	3	S
21588	Gleevec	Imatinib Mesylate	Novartis	3	P
21503	Viracept	Nelfinavir Mesylate	Agouron	3	S
21399	Iressa	Gefitinib	AstraZeneca	1	P
21602	Velcade	Bortezomib	Millennium Pharms	1	P
21455	Boniva	Ibandronate Sodium	Roche	1	S
21496	Duocaine	Bupivacaine Hydrochloride; Lidocaine Hydrochloride	Amphastar Pharms	4	S
20800	Twinject	Epinephrine	Hollister-Stier Labs	3	S
21528	Acular LS	Ketorolac Tromethamine	Allergan	3	S
21396	Prempro/Premphase	Conjugated Estrogens; Medroxyprogesterone Acetate	Wyeth Pharms	3	S
21532	Benicar HCT	Olmesartan Medoxomil; Hydrochlorothiazide	Sankyo Pharma	4	S
21137	Levolet	Levothyroxine Sodium	Vintage Pharms	5	S
21485	Stalevo	Carbidopa; Levodopa; Entacapone	Orion	4	S
21287	Uroxatral	Alfuzosin Hydrochloride	Sanofi Synthelabo	1	S
21559	Infuvite Adult	Multiple Vitamins	Sabex	5	S
21543	Striant	Testosterone	Columbia Labs	3	S
21229	Prilosec	Omeprazole Magnesium	AstraZeneca LP	2,3	S
			Bristol Myers		

21567	Reyataz	Atazanavir Sulfate	Squibb	1	P
21387	Pravigard PAC	Aspirin;Pravastatin Sodium	Bristol Myers Squibb	4	S
21500	Emtriva	Emtricitabine	Gilead	1	S
21299	Paroxetine Mesylate	Paroxetine Mesylate	Synthon Pharms	2	S
20452	Paraplatin	Carboplatin	Bristol Myers Squibb	3	S
21505	Keppra	Levetiracetam	UCB Pharma	3	S
21417	Premarin	Conjugated Estrogens	Wyeth Pharms	3	S
21537	Ciprodex	Ciprofloxacin;Dexamethasone	Alcon	3	S
21535	Clobex	Clobetasol Propionate	Galderma Labs LP	3	S
21372	Aloxi	Palonosetron Hydrochloride	Helsinn Hlthcare	1	S
21546	Rebetol	Ribavirin	Schering	3	P
21348	Zavesca	Miglustat	Actelion	1	SV

Chemical Types:

- 1 - New molecular entity
- 2 - New ester, new salt, or other noncovalent derivative
- 3 - New formulation
- 4 - New combination
- 5 - New manufacturer
- 6 - New indication (Beginning in 1994, Type 6's were tracked as efficacy supplements, not as NDAs.)
- 7 - Drug already marketed, but without an approved NDA

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

S - Standard Review - The drug appears to have therapeutic qualities similar to those of one or more already marketed drugs.

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Page Last Updated: August 13, 2003

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